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09/992,957Applicant: **Hans Herweijer, et al.**

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## U.S. PATENT DOCUMENTS

Exmnr Intl	Seq	Patent Number	Issue Date	Patentee	Class	Sub Class	Filing Date

## FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

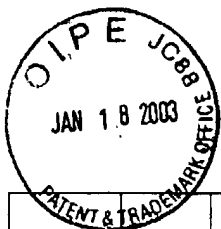
		Document Number	Publ. Date	Country or Patent Office	Class	Sub Class	Transl. Yes No	

## OTHER DOCUMENTS (Including Author, Title, Date Pertinent Pages, etc.)

<b>DS</b>		Svoboda et al., "RNAi in mouse oocytes and preimplantation embryos: effectiveness of hairpin dsRNA," Biochemical and Biophysical Research Communication; 2001, vol. 287, pp. 1099-1104
		Trubetskoy et al., "quantitative assessment of DNA condensation," Analytical Biochemistry; 1999, vol. 267, pp. 309-313
		Suter et al., "BAC-VAC, a novel generation of (DNA) vaccines: A bacterial artificial chromosome (BAC) containing a replication-competent, packaging -defective virus genome induces protective immunity against herpes simplex virus 1," PNAS; 1999, vol. 96 no. 22, pp. 12697-12702
		Trubetskoy et al., "Layer-by-layer deposition of oppositely charged polyelectrolytes on the surface of condensed DNA particles," Nucleic Acids Research; 1999, vol. 27, no. 15, pp. 3090-3095
		Trubetskoy et al., "Self-assembly of DNA-polymer complexes using template polymerization," Nucleic Acids Research; 1998, vol. 26, no. 18, pp. 4178-4185
		Trubetskoy et al., "Caged DNA does not aggregate in high ionic strength solutions," Bioconjugate Chem; 1999, vol. 10, pp. 624-628
		Krieg et al., "The role of CpG dinucleotides in DNA vaccines," Trends in Microbiology; 1998, vol. 6, no. 1, pp. 23-7
<b>PS</b>		Lipford et al., "Bacterial DNA as immune cell activator," Trends in Microbiology; 1998,

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		vol. 6, no. 12, pp 496-500
88		Akbari et al., "DNA vaccination: transfection and activation of dendritic cells as key events for immunity," The Rockefeller University Press; 1999, vol. 189, no. 1, pp. 169-177
		Iwasaki et al., "Enhanced CTL responses mediated by plasmid DNA immunogens encoding costimulatory molecules and cytokines," The Journal of Immunology; 1997, vol. 158, pp. 4591-4601
		Etchart et al., "Class I-restricted CTL induction by mucosal immunization with naked DNA encoding measles virus haemagglutinin," Journal of General Virology; 1997, vol. 78, pp. 1577-1580
		Herrmann et al., "Immune responses and protection obtained by oral immunization with rotavirus VP4 and VP7 vaccines encapsulated in microparticles," Virology; 1999, vol. 259, pp. 148-153
		Kaneko et al., "Oral DNA vaccination promoted mucosal and systemic immune responses to HIV envelope glycoprotein," Virology; 2000, vol. 267, pp. 8-16
		Chen et al., "Protective immunity induced by oral immunization with a rotavirus DNA vaccine encapsulated in microparticles," Journal of Virology; 1998, pp. 5757-5761
		Gregoriadis et al., "Liposome-mediated DNA vaccination," REBS Letters; 1997, vol. 402, pp. 107-110
		MacGregor et al., "First Human Trial of a DNA-Based Vaccine for Treatment of Human Immunodeficiency Virus Type 1 Infection: Safety and Host Response," The Journal of Infectious Diseases; 1998, vol. 178, pp. 92-100
		Donnelly et al., "DNA Vaccines," Life Sciences; 1997, vol. 60, no. 3, pp. 163-172
		Tomasi "Introduction: an overview of the mucosal system," Handbook of Mucosal Immunology
		Fasano "Novel approaches for oral delivery of macromolecules," Journal of Pharmaceutical Sciences; 1998, vol. 87, no. 11
		Jackson et al., "Preparation and properties of totally synthetic immunogens," Vaccine; 2000, vol. 18, pp. 355-361
		DeNoon et al., "Conference coverage (ECP) combination vaccines): CEO: Biotech Breakthrough could shake vaccine industry," Aidsweekly Plus; 1998
		DeNoon "Conference coverage (ECP! Combination vaccines) 2202 vaccine market: \$7 billion," newsrx.com; 1998
		Irache et al., "Bioadhesion of lectin-latex conjugates to rat intestinal mucosa," Pharmaceutical Research; 1996, vol. 13, no. 11
		Shefner et al., "A novel class of anti-DNA antibodies identified in BALB/c mice," The Rockefeller University Press; 1991, vol. 173, pp. 287-296
		Eilat et al., "Monoclonal antibodies to DNA and RNA from NZB/NZW F1 mice: antigenic specificities and NH2 terminal amino acid sequences," The Journal of Immunology; 1984, vol. 133, no. 1
		Katsumi et al., "Humoral and cellular immunity to an encoded protein induced by direct DNA injection," Human Gene Therapy; 1994, vol. 5, pp. 1335-1339
88		Gilkeson et al., "Specificity of anti-DNA antibodies induced in normal mice by immunization with bacterial DNA," Clinical Immunology and Immunopathology; 1991, vol. 59, pp. 288-300

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	Whiteside et al., "Clinical usefulness of the crithidia luciliae test for antibodies to native DNA," Anti-DS DNA in Disease; vol. 72, no. 5
	Tron et al., "Relationships between antibodies to native DNA and glomerulonephritis in systemic lupus erythematosus," Clin. Exp. Immunol; 1977, vol. 28, pp.426-432
	Nakamura et al., "Microhemagglutination test for detection of antibodies to nuclear sm and ribonucleoprotein antigens in systemic lupus erythematosus and related diseases," Detection of sm and RNP antibodies; 1978, vol. 70, no. 5
	Wolff et al., "Long-term persistence of lasmid DNA and foreign gene expression in mouse muscle," Human Molecular Genetics; 1992, vol. 1, no. 6, pp. 363-369
	Liebert et al., "What about those monkeys that got T-Cell lymphoma," Human gene Therapy; 1993, vol. 4, pp. 1-2
	Liebert et al., "Saftey issues related to retroviral-mediated gene transfer in humans," Human Gene Therapy; 1991, vol. 2, pp. 5-14
	Lahijani et al., "Quantitation of host cellDNA contaminate in pharmaceutical-grade plasmid DNA using competitive polymerase chain reaction and enzyme-linked immunosorbent assay," Human Gene Therapy; 1998, vol. 9, pp. 1173-1180
	Lahijani et al., "High-yield production of pBR322-derived plasmids intended for human gene therapy by employing a temperature-controllable point mutation," Human Gene Therapy; 1996, vol. 7, pp. 1971-1980
	Boyle "Disease and fertility control in wildlife and feral animal populations: options for vaccine delivery using vectors," Tepad. Fertil. Dev.; 1994, vol. 6, pp. 393-400
	Sato et al., "Immunostimulatory DNA sequences necessary for effective intradermal gene immunization," Science; 1996, vol. 273
	Roman et al., "Immunostimulatory DNA sequences function as T helper-1-promoting adjuvants," Nature Medicine; 1997, vol. 3, no. 8
	Leclerc et al., "The preferential induction of a TH1 immune response by DNA-based immunization is mediated by the immunostimulatory effect of plasmid DNA," Cellular Immunology; 1997, vol. 179, pp. 97-106
	Fu et al., "Primin of cytotoxic T lymphocytes by DNA vaccines: requirement for professional antigen presenting cells and evidence for antigen transfer from myocytes," Molecular Medicine; 1997, vol. 3, no. 6, pp. 362-371
	Kim et al., "Engineering of in vivo immune responses to DNA immunization via codelivery of costimulatory molecule genes," Nature Biotechnology; 1997, vol. 15, pp. 641-646
	Chow et al., "Development of TH1 and Th2 populations and the nature of immune responses to hepatitis B virus DNA vaccines can be modulated by codelivery of various cytokine genes," The Journal of Immunology; pp.1320-1329
	Xiang et al., "Manipulation of the immune response to a plasmid-encoded viral antigen by coinoculation with plasmids expressing cytokines," Immunity; 1995, vol. 2, pp. 129-135
	Pardoll et al., "Exposing the immunology of naked DNA vaccines," Immunity; 1995, vol. 3, pp. 165-169
	Quong et al., "DNA protection form extracapsular nucleases, within chitosan- or poly-l-lysine-coated alginated beads,"
DS	Roy et al., "oral gene delivery with chitosan-DNA nanoparticles generates immunologic protection in a murine model of peanut allergy," Nature Medicine; 1999, vol. 5, no. 4, pp. 387-391

DS Cl 3/18/04



PS	Alapar et al., "Potential of particulate carriers for the mucosal delivery of DNA vaccines," Biochemical Society Transactions; 1997, vol. 25, p. 337S
	Jones et al., "Poly(DL-lactide-co-glycolide)-encapsulated plasmid DNA elicits systemic and mucosal antibody responses to encoded protein after oral administration," Vaccine, 1997, vol. 15, no. 8, pp. 814-817
	Ermak et al., "Uptake and transport of copolymer biodegradable microspheres by rabbit peyer's patch M cells," Cell Tissue Res; 1995, vol. 279, pp. 433-436
	Florence et al., "Factors affecting the oral uptake and translocation of polystyrene nanoparticles: histological and analytical evidence," Journal of Drug Targeting; 1995, vol. 3, pp. 65-70
	Bockman et al., "Pinocytosis by epithelium associated with lymphoid follicles in the bursa of fabricius, appendix, and peyer's patches. An electron microscope study," Am. J. Anat.; vol. 136, pp. 455-478
	Mathiowitz et al., "Biologically erodable microspheres as potential oral drug delivery systems," Nature; 1997, vol. 386
	Ishii et al., "cationic liposomes are a strong adjuvant for a DNA vaccine of human immunodeficiency virus type 1," Aids Research and Human Retroviruses; 1997, vol. 13, no. 16, pp. 1421-1428
	Jiao et al., "Direct gene transfer into nonhuman primate myofibers in vivo," Human Gene Therapy; 1992, vol. 3, pp. 21-33
	Wang et al., "Induction of antigen-specific cytotoxic T lymphocytes in a humans by a malaria DNA vaccine," Science; 1998, vol. 282, pp. 476-480
	Ulmer et al., "Heterologous protection against influenza by injection of DNA encoding a viral protein," Science; 1993, vol. 259, pp. 745-749
	Acsadi et al., "Direct gene transfer and expression into rat heart in vivo," The New Biologist; 1991, vol. 3, no. 1, pp. 71-81
	Tang et al., "Genetic immunization is a simple method for eliciting an immune response," Nature; 1992, vol. 356, pp. 152-154
	Wolff et al., "Direct gene transfer into mouse muscle in vivo," Science; 1990, vol. 247, pp. 1465-1468
	Ulmer et al., "Generation of MHC class I-restricted cytotoxic T lymphocytes by expression of a viral protein in muscle cells: antigen presentation by non-muscle cells," Immunology; 1996, vol. 89, pp. 59-67
	Donnelly et al., "DNA vaccines," Annu. Rev. Immunol.; 1997, vol. 15, pp. 617-648
PS	Suhrbier "Multi-epitope DNA vaccines," Immunology and Cell Biology; 1997, vol. 75, pp. 402-408

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